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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------------|----------------------|---------------------|------------------|
| 10/612,770 | 07/01/2003 | James E. Brewer | A03P1047 | 4998 |
| 36802 DACESETTE | 7590 12/21/2006 | EXAMINER | | |
| PACESETTER, INC. 15900 VALLEY VIEW COURT | | | GEDEON, BRIAN T | |
| SYLMAR, CA | X 91392-9221 | | ART UNIT | PAPER NUMBER |
| • | | | 3766 | |
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| SHORTENED STATUTO | RY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 3 MC | ONTHS | 12/21/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) | | | |
|---|--|--|--|--|--|
| | 10/612,770 | BREWER ET AL. | | | |
| Office Action Summary | | | | | |
| • • • • • • • • • • • • • • • • • • • | Examiner | Art Unit | | | |
| - The MAILING DATE of this communication and | Brian T. Gedeon | orrespondence address | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was realized to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | • | | | | |
| 1) Responsive to communication(s) filed on 10/16/06. | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | This action is FINAL . 2b) This action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-22 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | vn from consideration. | | | | |
| Application Papers | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on 01 July 2003 is/are: a) Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex | ☑ accepted or b)☐ objected to be drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj | e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d). | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| ded the attached detailed effice detail for a list of the definited depice not received. | | | | | |
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| | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate | | | |

Application/Control Number: 10/612,770

Art Unit: 3766

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 1. Claims 1, 3, 5, 6, 11, and 14-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dahl et al. (US Patent no. 6,976,967).

In regard to the above claims, Dahl et al. disclose an apparatus and method for sensing spatial displacement in the heart. The Examiner considers spatial displacement to be a parameter of cardiac geometry. The medical device 300 according to the invention includes a first lead 302 and a second lead 304, col 4 lines 35-55, which can be mounted in the vasculature in or around the heart as well as in any of the four cardiac chambers. Figures 3 and 4 show the embodiments of the leads in different chambers of the heart. Figure 9 teaches that a signal is measured from a lead disposed in a structure of the heart, and determines a change in dimension of the heart due to the beating based on the detected signal, thereby anticipating the claimed method and devices. Further, Dahl et al. contains a housing 306 that inherently incorporates circuitry operable to supply electrical stimulation pulses to the electrodes on the implantable leads, 302 and 304.

Art Unit: 3766

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (US Patent no. 6,976,967).

In regard to claims 10-12, Dahl et al. substantially describe the invention as claimed except do no teach calculating a cardiac chamber volume or diameter from the claimed method. Dahl et al. do measure a chamber distance, from which one of ordinary skill in the art at the time the invention was made could calculate the related values of volume and diameter.

In regard to claim 13, Dahl et al. substantially describe the invention as claimed except do no teach that the cardiac geometry parameter determined gives an indication of congestive heart failure. However, Dahl et al. do teach that by measuring the changes in the distance of the heart, the function of the heart may be directly monitored, col 3 lines 60-62. The "function of the heart" implies that abnormalities and states of certain conditions, e.g. congestive heart failure, can be monitored from the measurements of displacement. Therefore it would be obvious.

Application/Control Number: 10/612,770 Page 4

Art Unit: 3766

3. Claims 2, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (US Patent no. 6,976,967) in view of Thacker (US Patent no. 5,024,222).

In regard to claims 2, 4, and 7, Dahl et al. substantially describe the invention as claimed except do not expressly teach the use of ring electrodes of unipolar pacing means. Thacker shows that ring electrodes and unipolar pacing means are well known in the cardiac pacing art. Therefore use of a ring electrode or unipolar pacing means would be obvious since they are well known in the art.

4. Claims 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahl et al. (US Patent no. 6,976,967) in view of Digby (US Patent no. 6,496,730).

In regard to claims 8 and 9, Dahl et al. substantially describe the invention as claimed except do teach sensing or pacing during the refractory period. Digby et al. show that sensing and pacing can occur during a refractory period, col 4 lines 1-10. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to sense and pace during the refractory period in order to artificially extend it.

Response to Arguments

5. Applicant's arguments, filed 16 October 2006, with respect to the rejection(s) of claim(s) 1-7, 10-12, and 14-20 under 35 U.S.C. 103(a) as being obvious over Sloman et al. (US Patent no. 6,738,669) in view of Budd et al. (US Patent 5,662,669) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Application/Control Number: 10/612,770

Art Unit: 3766

However, upon further consideration, a new ground(s) of rejection is made in view of Dahl et al. (US Patent no. 6,976,967).

6. The indicated allowability of claim 8, 9, and 21 is withdrawn in view of the newly discovered reference(s) to Dahl et al. (US Patent no. 6,976,967) and Digby (US Patent no. 6,496,730). Rejections based on the newly cited reference(s) are above.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

Art Unit: 3766

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon Patent Examiner Art Unit 3766 Robert E. Pezzuto Supervisory Patent Examiner Art Unit 3766

BTG